

**CDER GUIDANCES**  
**NEW/REVISED/WITHDRAWN**  
**1/1/2006 –2/28/2006**  
(Sorted by date)

<b>Title</b>	<b>Subject</b>	<b>Level at Date of Issue</b>	<b>Publication/Withdrawal Date</b>	<b>Status</b>
Recommended Approaches to Integration of Genetic Toxicology Study Results	Pharmacology Toxicology	Level 1	01/04/2006	New
M2: eCTD Specification Questions and Answers and Change Requests	Joint Safety/Efficacy	Level 2	01/06/2006	New
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice	CGMPs	Level 1	01/12/2006	New
Exploratory Investigational New Drug Studies	Pharmacology Toxicology	Level 1	01/17/2006	New
Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1	CGMPs Draft	Level 1	01/17/2006	New
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	01/24/2006	New
Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements	Labeling Draft	Level 1	01/24/2006	New
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling Draft	Level 1	01/24/2006	New
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims	Clinical Medical Draft	Level 1	02/03/2006	New

**CDER GUIDANCES**  
**NEW/REVISED/WITHDRAWN**  
**1/1/2006 –2/28/2006**  
(Sorted by date)

Nonclinical Safety Evaluation of Pediatric Drug Products	Pharmacology Toxicology	Level 1	02/15/2006	New
Reports on the Status of Postmarketing Study Commitments – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997	Procedural	Level 1	02/16/2006	New